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| 09/845,497 | 05/01/2001 | Amina Odidi | 9577-25 LAB | 2340 |

7590 08/04/2008
Lola A. Bartoszewicz
Sim & McBurney
6th Floor
330 University Avenue
Toronto, ON M5G 1R7
CANADA

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| EXAMINER |
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PRYOR, ALTON NATHANIEL

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| ART UNIT | PAPER NUMBER |
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1616

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08/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 09/845,497 | Applicant(s) ODIDI ET AL. | |
| | Examiner ALTON N. PRYOR | Art Unit 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-9,11,15-17,21-32 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6-9,11,15-17,21-32 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments filed 5/22/08 have been fully considered but they are not persuasive. See arguments below. Previous rejections and issues not discussed below have been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,6-9,15-17,21-32,34 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for invention comprising polymeric films: polyvinyl acetate phthalate, methacrylic acid copolymers, does not reasonably provide enablement for the polymeric film being cellulose esters. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Note instant invention requires the polymeric film to be non-permeable. The instant invention uses cellulose esters to formulate the non-permeable film. However USPN 6099859 at column 4 lines 10-28 and USPN 6106864 at column 4 lines 32-38 disclose that cellulose esters are semi-permeable rather than non-permeable.

Response to Applicant's argument

Applicant argues that Dolan (USPN 6106864) discloses that cellulose esters are semi-permeable rather than non-permeable. Dolan describes cellulose acetate as being

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both impermeable and semi-permeable. Applicant further argues "The cellulose esters chosen for the instant invention must be combined in the percentages claimed, and must provide the encasement coat with the features instantly claimed; be non-permeable and soluble in a pH of above about 5.0." Examiner argues that Applicant merely states that the correct percentages (claimed percentages) of cellulose esters would provide a non-permeable coat, which would be soluble in a pH of above about 5.0. However, Examiner further argues that Applicant does not provide experimental results to show that such a coat would be produced. Where the prior art shows uncertainty or suggest the opposite of the claimed invention, it is critical that applicant supports the invention claimed with experimental data.

The Applicant admits that cellulose acetate is a cellulose ester. The Applicant merely states without proof that an artisan would not consider using cellulose acetate in the encasement coat since cellulose acetate would dissolve and form a semi-permeable membrane at pH below 5. The Examiner argues that the claims are not limited to specific cellulose esters and that the Applicant does not support the cellulose dissolution statement with data. For these reasons the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,6-9,11,15-17,21-34 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Dolan et al (USPN 6106864; 8/22/00) and Dong et al (USPN 5800422; 9/1/98) and Cheng on record (USPN 6099859; 8/8/00). Dolan teaches oral dosage forms of actives such as darifenacin. See column 2 lines 34-52. Dolan teaches that the matrix comprising the active can be formed into a multiparticulate and / or coated with an impermeable coating. See column 2 lines 53-57. Dolan teaches that the multiparticulate cores comprising the actives can also contain cellulose and lactose (compression aids). See column 3 lines 1-7. Dolan teaches that the ingredients can be formulated into a tablet which can be coated with shellac, phthalate derivatives (cellulose acetate phthalate, polyvinylacetate phthalate) as well as with semi-permeable coatings such as cellulose esters (ethyl cellulose, cellulose acetate) and acrylic polymers. See column 3 lines 7-38. Dolan does not teach the polymeric coating comprising 1) 5 up to less than 50% by weight polymer, e.g. ethyl cellulose 2) 0.5 to 30% PEG. Dolan is silent to the amount of polymer in the coating. Therefore, in the absence of unexpected results showing the significance of the instantly claimed amount of polymer, the ideal amount of polymer used in Dolan may have fallen within the instant range of polymer amount being claimed. With respect to the polymeric film comprising PEG. Dong discloses the use of PEG in a capsule film coating. Note, Dong uses 25 % PEG in the polymer coating which falls within the instantly claimed range amount. Cheng teaches that PEG is a flux-enhancing agent. A flux-enhancing agent allows the drug to be released through the pores of the polymeric coating. It would have been obvious to one having ordinary skill in the art to modify the invention of Dolan to include

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the PEG to enhance the release of the drug through the pores of polymeric coating.

Although claims require the polymeric material to be non-permeable, it is noted that the claims employ polymeric films such as cellulose esters and acrylic polymers which are semi-permeable. For this reason the rejection appears to be proper. Note the property of the polymeric coating being soluble at a pH above 5.0 and having an extended release of the active over 12 hours are inherent properties of the polymer (cellulose esters) and PEG being used.

Response to Applicant's argument

The Applicant argues that Dolan does not teach / suggest an encasement coat being non-permeable as a whole and soluble in pH of above about 5. The Examiner argues that Dolan teaches that the active ingredients can be formulated into a tablet which can be coated with shellac, phthalate derivatives (cellulose acetate phthalate, polyvinylacetate phthalate) which are impermeable and soluble at a pH greater than 5 (Dolan column 3 lines 7-38). In the instant invention, where shellac or phthalate derivatives (cellulose acetate phthalate, polyvinylacetate phthalate) serve as the coating materials the limitation of the invention with respect to the coating is met. Note, the instant specification employs said polymers as coating materials (specification paragraph 39).

Other Matters

In light of documentation provided, the Examiner agrees that ethyl cellulose is not a cellulose ester.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alton N. Pryor/
Primary Examiner, Art Unit 1616